UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

IN RE: DEPUY ORTHOPAEDICS, INC. PINNACLE HIP IMPLANT PRODUCT LIABILITY LITIGATION	)	MDL No. 2244
This Document Relates To:	)	Honorable Ed Kinkeade
Andrews v. DePuy Orthopaedics, Inc., et al. No. 3:15-cv-03484-K	)	
Davis v. DePuy Orthopaedics, Inc., et al. No. 3:15-cv-01767-K	)	
Metzler v. DePuy Orthopaedics, Inc., et al. No. 3:12-cv-02066-K	)	
Rodriguez v. DePuy Orthopaedics, Inc., et al. No. 3:13-cv-03938-K	)	
Standerfer v. DePuy Orthopaedics, Inc., et al. No. 3:14-cv-01730-K	)	
Weiser v. DePuy Orthopaedics, Inc., et al. No. 3:13-cv-03631-K	)	

DEFENDANTS' REPLY IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF PLAINTIFFS' EXPERTS REGARDING THE PURPORTED RISK OF SYSTEMIC ILLNESS ASSOCIATED WITH METAL-ON-METAL HIP IMPLANTS

Plaintiffs' opposition only serves to underscore the necessity of precluding their experts from discussing any supposed risk of cancer or other systemic illness from metal-on-metal implants at trial. In their brief, plaintiffs concede that their experts will not testify that any of the plaintiffs is at an increased risk of cancer as a result of having a metal-on-metal hip implant. Indeed, ***they concede that the risk of cancer or systemic illness is unknown***. Nevertheless, plaintiffs argue that because "those risks cannot be disregarded," plaintiffs' experts "will opine that continued monitoring of patients following exposure is prudent." (Pls.' Opp'n at 1.) The Court should reject their arguments for several reasons.

First, this is just the latest example of plaintiffs' trial-by-ambush strategy. Rule 26(a) of the Federal Rules of Civil Procedure requires an expert to provide "a ***complete statement*** of all opinions the witness will express and the basis and reasons for them." *See* Fed. R. Civ. P. 26(a)(2)(B) (emphasis added). As the Fifth Circuit has recognized, "the purpose of the reports is to avoid the disclosure of 'sketchy and vague' expert information." *Sierra Club, Lone Star Chapter v. Cedar Point Oil Co.*, 73 F.3d 546, 571 (5th Cir. 1996) (quoting Fed. R. Civ. P. 26 advisory committee's note). Any opinions not included in expert reports should be barred from trial. *See Sobrino-Barrera v. Anderson Shipping Co.*, 495 F. App'x 430, 433 (5th Cir. 2012) (affirming district court's exclusion of expert opinions that "were not included in [the expert's] expert report"); *Hill v. Koppers Indus.*, No. 3:03CV60-P-D, 2009 U.S. Dist. LEXIS 98798, at *34, *37-40 (N.D. Miss. Sept. 30, 2009) (striking expert testimony where deponent "produced or referenced new information that contributed to his opinion that he admitted he had not disclosed before the deposition"); *X-Tra Light Mfg. Inc. v. Acuity Brands, Inc.*, No. H-04-1413, 2007 U.S. Dist. LEXIS 99281, at *3 (S.D. Tex. Feb. 13, 2007) ("[E]xpert opinions not fully disclosed in an expert report should not be introduced at trial.").

None of plaintiffs' experts disclosed any opinions regarding the need for monitoring in their reports. (In fact, several of their experts did not produce a proper report at all.) Nor did plaintiffs' experts even offer monitoring opinions at their depositions. As a result, defendants have no idea what kind of monitoring by what kind of physician and for how long plaintiffs' experts believe is necessary. Among other things, defendants do not know whether plaintiffs' experts are suggesting that plaintiffs should be monitored by oncologists for future cancer risk, by nephrologists for kidney damage, or by their revising physicians for changes in their serum ion levels. Plaintiffs state – in a footnote – that the experts' reports "suggest" that "they will

opine that patients exposed to cobalt and chromium ions should continue to be monitored by their physicians[.]" (Pls.' Opp'n at 2 n.2.) But the federal rules require disclosures, not suggestions. And none of the citations plaintiffs include even mentions the word monitoring or any related concept; at most, they cite to Dr. Matthew Morrey's general opinion that "physicians are tasked with taking care of their patients." (*Id.*)

The discovery rules were specifically designed to prevent this sort of surprise by requiring experts to provide "the opposing parties with notice of the scope of the expert's testimony" so that those parties have the opportunity to cross-examine the expert during his or her deposition and/or "retain an opposing expert." *Honey-Love v. United States*, No. H-14-2185, 2016 WL 1171483, at *3 (S.D. Tex. Jan. 21, 2016); *see Hill*, 2009 U.S. Dist. LEXIS 98798, at *40 (experts must disclose "all the relevant information in a timely fashion so that the opposing party may prepare to cross-examine the expert during his or her deposition"). Because these experts failed to mention at any point during the discovery process that they would offer such opinions, defendants had no opportunity to explore the bases for and scope of these opinions. For this reason alone, plaintiffs' experts should not be allowed to testify about cancer or any other systemic illness at trial.

Second, plaintiffs' concession that it is ***unknown*** whether patients with metal-on-metal hip implants face any risk of future systemic illness should alone shut the door on any evidence – particularly "expert" evidence – related to such a risk. As defendants set forth in their opening brief, in order to be admissible, expert opinions "'must be supported by appropriate validation – i.e., ***"good grounds," based on what is known***,'" *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 275 (5th Cir. 1998) (emphasis added) (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589-90 (1993)). This is particularly true where an expert seeks to opine on the risk of

illness from exposure to a substance. (*See* Defs.' Mem. at 12-13 (collecting authorities).) Such testimony cannot be based on a "hypothesis," *see Porter v. Whitehall Labs., Inc.*, 9 F.3d 607, 614-15 (7th Cir. 1993), or on a theory that needs "'further stud[y],'" *Current v. Atochem N.A., Inc*., No. W-00-CA-332, 2001 WL 36101283, at *4 (W.D. Tex. Nov. 30, 2001) (citation omitted).

While plaintiffs argue that their experts' conjecture regarding the risk of systemic illness is exempt from these requirements because they will only testify that the risk is "unknown" – rather than heightened – plaintiffs offer no support for allowing such speculative, unhelpful expert testimony to reach a jury. In fact, courts have held that expert testimony regarding unknown and speculative injuries does ***not*** constitute reliable, scientific expert testimony. *See, e.g.*, *Rosa v. TASER Int'l, Inc.*, 684 F.3d 941, 946-47 (9th Cir. 2012) ("[R]eports of isolated or speculative injuries do not constitute generally accepted medical knowledge."); *Wehmeier v. UNR Indus., Inc*., 572 N.E.2d 320, 338-39 (Ill. App. Ct. 1991) (trial court erred by admitting speculative evidence regarding a risk of contracting cancer as a result of asbestos exposure); *see also Hess v. A.I. Dupont Hosp. for Children*, No. 08-0229, 2009 U.S. Dist. LEXIS 19492, at *35-36 (E.D. Pa. Mar. 5, 2009) (plaintiff's theory regarding future harm failed where he had "not produced any evidence that he [was] at an increased risk for anything, let alone medical expert testimony that he [was] a certain percentage more likely to suffer a certain affliction as a result of the [Cheatham Platinum covered] stent" because "***an unknown future is not a legally cognizable injury***") (emphasis added).

That result is especially appropriate here because the results of 30 years' worth of epidemiological studies ***are known***, and they do ***not*** show a causal relationship between metal-on-metal implants and cancer. (*See* Dep. of Matthew Morrey, M.D. 320:3-23, Sept. 14, 2016

(attached to Defs.' Mem. as Ex. 4) (Defs.' Mem. Appendix p. 324) (conceding that 30 years' worth of epidemiological studies have not shown a relationship between metal-on-metal implants and cancer).) *See also, e.g.*, Visuri, T.I. et al., *Cancer incidence and causes of death among total hip replacement patients: a review based on Nordic cohorts with a special emphasis on metal-on-metal bearings.* Proc. Inst. Mech. Eng. [H], 2006; 220:399, 402 ("The annual incidence of cancers of the [metal-on-metal] patients did not deviate from that of the general population for a follow-up time of 28 years."). And the international medical community has reached the conclusion that "[r]outine monitoring of metal ions after removal of [metal-on-metal] bearings is not recommended, as no effective interventions can currently be recommended in the case of increased metal ions." *See* Consensus Statement, *Current Evidence on the Management of Metal-on-Metal Bearings*, Apr. 16, 2012 (attached as Ex. 1) (Appendix p. 4).

Plaintiffs nonetheless contend that they "do not have the luxury of waiting to see whether systemic injuries will manifest, and what scientists may discover about the long-term systemic risks of metal-on-metal hips" because they must present their claims and damages now. (Pls.' Opp'n at 15.) But courts have previously rejected similar arguments, recognizing that they "may only admit the state of science as it is." *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1202 (11th Cir. 2002). "Law lags science; it does not lead it." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996); *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 677-78 (6th Cir. 2010) (permitting expert to opine that the manufacturers' products triggered "manganese-induced parkinsonism" inappropriately "allow[ed] the law to get ahead of science"). This blackletter rule of law reflects that there are "important differences between the quest for truth in the courtroom and the quest for truth in the laboratory." *Daubert*, 509 U.S. at 596-97. "Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and

quickly." *Id.* at 597. As such, the Court should not permit plaintiffs to support their claims against defendants with the specter of cancer and other systemic illnesses for which there is no scientific support.

Third, plaintiffs are also wrong that an opinion about the need for monitoring is "not governed by *Daubert*" because it is "tantamount to an opinion on the standard of care." (Pls.' Opp'n at 12.) Plaintiffs' sole basis for this remarkable position is their own misreading of *Phillips v. United States*, No. SA-08-CA-0619-XR, 2009 WL 3297967, at *1, *3 (W.D. Tex. Oct. 13, 2009). Citing to *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999), the court in *Phillips* merely held that the "*Daubert* factors typically used to evaluate expert testimony [did] not apply" because the expert's opinion at issue was based on his professional experience. *Phillips*, 2009 WL 3297967, at *3. Thus, as the portion of *Kumho Tire* cited by the court confirms, *Phillips* only stands for the uncontroversial position that the factors delineated by the U.S. Supreme Court in *Daubert* were meant to help guide courts in their gatekeeping duties and not serve as a "'definitive checklist.'" *See Kumho Tire*, 526 U.S. at 150 (citation omitted). Neither *Phillips* nor *Kumho Tire* suggests that *Daubert*'s reliability requirements do not apply at all; to the contrary, *Kumho Tire* expressly states that many "of *Daubert*'s questions can help to evaluate the reliability even of experience-based testimony." *Id.* at 150-51 ("We must therefore disagree with the Eleventh Circuit's holding that a trial judge may ask questions of the sort *Daubert* mentioned only where an expert 'relies on the application of scientific principles,' but not where an expert relies 'on skill- or experience-based observation'") (citation omitted). If plaintiffs were correct that physicians could always escape *Daubert* scrutiny by dressing up their opinions as statements about the "standard of care," the gates that guard against junk science

would be thrown open, welcoming all manner of quack medicine and unsubstantiated concern about hypothetical future risks.

In any event, plaintiffs' experts do not have the experience necessary to render opinions about the need to monitor metal-on-metal patients for systemic illnesses like cancer. While plaintiffs argue that all of the experts are qualified to render such opinions, each of the experts conceded that he does not have the expertise or information necessary to determine at what levels metal ions begin to create such a risk. (*See* Defs.' Mem. at 8-15.) And two of them (Drs. Burstein and Kessler) are not even practicing physicians.[1]

Finally, any opinions about the need for monitoring should also be excluded under Rules 401 and 403 because they are irrelevant and unfairly prejudicial. Plaintiffs argue that their experts' monitoring decisions are relevant "to the determination of damages" for "past and future mental anguish." (Pls.' Opp'n at 14-15.) However, as set forth in defendants' motion in limine (Defs.' MIL No. 18 at 41-46, *Andrews* ECF No. 59), in order to recover damages for fear of contracting a disease, plaintiffs must prove that there is either "a reasonable medical possibility that injuries of the kind they have suffered give rise to cancer" or, if the potential for cancer is not parasitic of their injury, that their fear of future illness stems from "reliable medical or scientific opinion." *Barron v. Martin-Marietta Corp.*, 868 F. Supp. 1203, 1212 (N.D. Cal.

[1] Plaintiffs also extensively quote the testimony of defendants' expert Dr. Eric Matthew Heinrich from the *Aoki* trial as ostensible support for the notion that "patient monitoring is appropriate." (Pls.' Opp'n at 7-8.) But plaintiffs misrepresent the nature of his testimony. Plaintiffs quote Dr. Heinrich as stating that "'it's appropriate to monitor' elevated ion levels even if other symptoms are normal." (*Id.* (quoting Dep. of Eric Matthew Heinrich, M.D. ("Heinrich Dep.") 354:22-356:22, Sept. 28, 2015 (attached to Pls.' Opp'n as Ex. 12) (Pls.' Opp'n Appendix pp. 241-43)).) But Dr. Heinrich provided that testimony in response to a question about whether he would recommend ***revision surgery*** to a patient who exhibited elevated levels of cobalt with no other symptoms – not whether he would recommend monitoring for a patient who no longer has a metal-on-metal hip implant. (Heinrich Dep. 354:22-358:23 (Pls.' Opp'n Appendix pp. 241-45).)

1994). Plaintiffs cannot and do not even attempt to do so because they concede that the risk is unknown.

Such evidence is also irrelevant because plaintiffs do not seek medical monitoring in their Complaints. Instead, they seek only damages for the "reasonable value of medical expenses that will necessarily be incurred ***in the care and treatment of [plaintiffs'] injuries*** beyond the time of trial." (*See, e.g.*, *Andrews* Am. Compl. ¶ 168(c) (emphasis added).) And even if plaintiffs had pled claims for medical monitoring, they would be unsustainable. Under California law, recovery for medical monitoring is "not available solely upon proof of an exposure to toxic chemicals." *Potter v. Firestone Tire & Rubber Co.*, 863 P.2d 795, 823 (Cal. 1993). Rather, it is only a compensable item of damages where "the need for future monitoring is a ***reasonably certain consequence*** of a plaintiff's toxic exposure." *Id.* at 824 (emphasis added). Specifically, a "plaintiff must demonstrate sufficient severity of exposure," which entails showing both the "significance and extent" of the exposure. *Riva v. Pepsico, Inc.*, 82 F. Supp. 3d 1045, 1057 (N.D. Cal. 2015). Given their concession that the risk of cancer and other systemic illnesses is unknown, plaintiffs admittedly have no evidence to support such a claim.

In truth, the only reason plaintiffs want to introduce this evidence is to scare the jury and arouse their sympathy, as evidenced by their highly improper use of evidence about cancer during the *Aoki* trial. (*See* 1/27/16 *Aoki* Trial Tr. 86:15-25 (Dr. Bernard Morrey professing a worry that was a "***hypothetical***" and "***theoretical concern***," unsupported by scientific evidence) (emphases added) (attached as Ex. 2) (Appendix p. 9); *id.* 234:10-14 (Ms. Aoki testifying: A: "And I – I didn't hear about the cancer until we were here." Q: "And now that you know that's in you?" A: "Well, makes me think maybe I should spend some of my 401(k).") (Appendix p. 10).) This type of presentation improperly invites the jury to hold defendants liable and award

inflated damages based purely on speculation of future harm. *See, e.g.*, *Adams v. Johns-Manville Sales Corp.*, 783 F.2d 589, 591 (5th Cir. 1986) (affirming district court's exclusion of all evidence related to plaintiff's "alleged increased risk of cancer" because "'[t]here can be no causal link with an injury when that injury hasn't yet occurred,'" particularly when plaintiff lacks "proof of medical probability that [plaintiff] would contract cancer in the future") (citation omitted); *Coursen v. A.H. Robins Co.*, 764 F.2d 1329, 1331 (9th Cir. 1985) (affirming district court's holding that, "where plaintiffs' claims were limited to injuries associated with pregnancy, any testimony regarding other possible injuries to, or other side effects suffered by, users of the [product] would be inadmissible as irrelevant, prejudicial, collateral, and potentially confusing").

For all of these reasons, the Court should preclude plaintiffs' experts from offering any testimony about the risk – known or unknown – of cancer or other systemic illness and/or the monitoring that they now "suggest" is necessary.

CONCLUSION

For the foregoing reasons, defendants respectfully request that the Court preclude Drs. Bernard Morrey, Matthew Morrey, David A. Kessler, and Albert H. Burstein and any other witnesses from opining about the supposed risk of cancer or any other systemic illness from metal-on-metal implants.

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Respectfully submitted,

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